

REMARKS:

Applicant has carefully studied the nonfinal Examiner's Action and all references cited therein. The amendment appearing above and these explanatory remarks are believed to be fully responsive to the Action. Accordingly, this important patent application is now believed to be in condition for allowance.

Applicant responds to the outstanding Action by centered headings that correspond to the centered headings employed by the Office, to ensure full response on the merits to each finding of the Office.

Claim Rejections – 35 U.S.C. § 112

Applicant acknowledges the quotation of 35 U.S.C § 112, second paragraph.

Claims 1-25 stand rejected under 35 U.S.C § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. More specifically, independent claim 1 stands rejected for the use of the term "substantially simultaneous". The Office contends that this is a relative term which is not defined by the claim and the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 1 has been amended to overcome the 35 U.S.C § 112.

Claim Rejections – 35 U.S.C. § 102

Applicant acknowledges the quotation of 35 U.S.C § 102(e).

Claims 1-3, 5, 8 and 20-22 stand rejected under 35 U.S.C § 102(e) as being anticipated by Hofmann WO 99/62592.

The Office contends, with reference to claim 1, that Hofman discloses a method of electromanipulation for effecting simultaneous electroporation and electromigration of molecules into cells by applying to a cellular target a preselected waveform at pg. 7, lines 22-24. Applicant respectfully traverses the finding of the Office.

Hofmann states at pg. 7, lines 22-24 that a first electric impulse is applied to collect charged preselected molecules at regions near the cell membrane and then a second electric impulse is applied to permeabilize the cell membrane forming transient pores. Hofman further describes at pg. 2, line 10-12, a three-step pulse process, wherein the three-step pulse includes three discrete electrical impulses each having a specified duration and strength to achieve its respective function. Hofmann additionally describes at pg. 7, lines 17-24, a three-step pulse process, e.g. collection, electroporation, electrophoresis, which is use to introduce preselected molecules into the cell. Hofmann describes the three-step pulse as including three discrete impulses having a specified duration and strength to achieve its respective function.

The description provided by Hofmann clearly indicates the use of three discrete pulses, each pulse providing a respective function. As indicated by Hofmann, a first pulse of a specified duration and strength is effective in the collection of molecules to a specified location, a second pulse of a specified duration and strength is effective in the electroporation of the cells and a third pulse of a specified duration and strength is effective in the electrophoresis of the cell. As such, the three-step pulse method described by Hofmann is not equivalent to the method in accordance with the present invention as disclosed and claimed.

Currently amended claim 1 recites a method of electromanipulation provided for effecting electroporation coincident with electromigration of molecules into cells by applying an electrical pulse to a cellular target, the application of the pulse commencing at a pulse initiation time and concluding at a pulse termination time, the application of the pulse occurring between the pulse initiation time and the pulse termination time thereby defining a pulse duration, the electrical pulse further comprising a predetermined waveform, wherein the predetermined waveform further comprises at least two continuous waveform components, wherein each of the at least two continuous waveform components further comprises a predetermined voltage level and a predetermined component duration. The current amendment is supported by the

specification wherein the waveform of the present invention is described as a continuous waveform having various waveform components. As described in paragraph [0066], the continuous waveform is a single pulse and therefore it is inherent that the pulse have an initiation time and a termination time.

In contrast, Hofmann clearly describes a three-step pulse wherein each three-step pulse includes three discrete electrical impulses having a specified duration and strength. As such, each discrete electrical impulse within the three-step pulse as taught by Hofmann would inherently include multiple initiation times and termination times with each pulse having a specified duration. By contrast, the present invention describes the application of a waveform having at least two components wherein the pulse duration, as identified by the pulse initiation time and the pulse termination time is a sum of the waveform component durations included in electrical pulse. As such, in accordance with the present invention, an electrical pulse is applied for a specified duration wherein the electrical pulse further comprises a plurality of waveform components each have a specified duration. With this method, the discomfort to the patient is reduced because it is only necessary to initiate the pulse once. The selection of the waveform components is effective in providing electromigration and electroporation during the period identified by the initiation time and the termination time. By contrast, the patent to Hofmann would require that the patient be shocked three times during the application of three-step pulse as described.

For the reasons cited above, Applicant believes that amended independent claim 1 is not anticipated by Hofmann and is believed to be in condition for allowance.

Claim Rejections – 35 U.S.C. § 103

Applicant acknowledges the quotation of 35 U.S.C § 103(a).

Claims 4, 6, 7, 9-19 and 23-25 stand rejected under 35 U.S.C § 103(a) as being unpatentable over Hofmann WO 99/62592 in view.

For the reasons cited above with reference to the 35 U.S.C. 102 rejection, Applicant believes that amended independent claim 1 is patentable over Hofmann believed to be in condition for allowance.

Claims 2-25 are dependent upon claim 1, which has been shown to be allowable, and are therefore allowable as a matter of law.

If the Office is not fully persuaded as to the merits of Applicant's position, or if an Examiner's Amendment would place the pending claims in condition for allowance, a telephone call to the undersigned at (727) 507-8558 is requested.

Very respectfully,

SMITH & HOPEN

By: 

Anton J. Hopen
15950 Bay Vista Drive, Suite 220
Clearwater, FL 33760
(727) 507-8558
Attorneys for Applicant

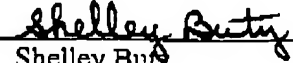
Dated: March 30, 2004

CERTIFICATE OF FACSIMILE TRANSMISSION

(37 C.F.R. 1.8(a))

I HEREBY CERTIFY that this Amendment A is being transmitted by facsimile to the United States Patent and Trademark Office, Art Unit 3762, Attn.: Roderick D. Bradford, (703) 872-9302 on March 30, 2004.

Dated: March 30, 2004


Shelley Butz